UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,554	11/28/2001	Andreas Manz	50225-8066.US08	1440

22918 7590 09/27/2005

PERKINS COIE LLP
P.O. BOX 2168
MENLO PARK, CA 94026

EXAMINER	
NOGUEROLA, ALEXANDER STEPHAN	

ART UNIT	PAPER NUMBER
1753	

DATE MAILED: 09/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/995,554	MANZ ET AL.	
	Examiner	Art Unit	
	ALEX NOGUEROLA	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *amednment of July 07, 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *46-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *46-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 November 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 08/226,605.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 46-63 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. New claim 46 requires "means for electrokinetically injecting a sample into the device which reflects the original sample composition [emphasis added]." While Applicants have support in the original disclosure for means for electrokinetically injecting a sample into the electrolyte channel from the supply channel which reflects the original sample composition, no support has been found for quoted limitation.

3. Claims 46-63 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are those present in the first full

paragrraph on page 7 of the specification. Verheggen (cited on the IDS of August 26, 2002) discloses a microfluidic device that meets all of the limitations of claim 1 except that the means for electrokinetically injecting a sample into the electrolyte channel from the supply channel does *not* reflect the original sample composition. See the abstract; Figure 1 and the last three sentences in the first paragrraph of "Discussion" on page 622. this implies missing critical elements or steps from claim 46. What is missing are critical steps. As stated on page 7 of the specification, "In order to assure that the composition of the sample in the sample volume 27 reflects the actual sample composition in the reservoir R" several specified steps must be performed.

4. Note that dependent claims will have the deficiencies of base and intervening claims.

Double Patenting

Double Patenting Rejections based on U.S. Patent No. 6,423,198 B1

5. Claim 46 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,423,198 B1. Although the conflicting claims are not identical, they are not patentably distinct from

each other because the method of claim 1 of U.S. Patent No. 6,423,198 B1 uses a device that meets the limitations of claim 46 of the instant application.

6. Claim 47 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claims 1 and 12 of U.S. Patent No. 6,423,198 B1. Claim 46, from which claim 47 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because the device of claim 12 of U.S. Patent No. 6,423,198 B1 requires the supply and drain channels to each be inclined with respect to the channel they intersect.

7. Claim 48 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claims 1 and 12 of U.S. Patent No. 6,423,198 B1. Claim 46, from which claim 48 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because the device of claim 12 of U.S. Patent No. 6,423,198 B1 requires the additional limitation of claim 48 of the instant application.

8. Claim 49 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 8 of U.S. Patent No. 6,423,198 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of claim 8 of U.S. Patent No. 6,423,198 B1 uses a device that meets the limitations of claim 49 of the instant application.

9. Claim 50 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 9 of U.S. Patent No. 6,423,198 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of claim 9 of U.S. Patent No. 6,423,198 B1 uses a device that meets the limitations of claim 50 of the instant application.

10. Claim 51 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claims 9 and 19 of U.S. Patent No. 6,423,198 B1. Claim 50, from which claim 51 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because the device of claim 19 of U.S. Patent No. 6,423,198 B1 provides the additional limitation of claim 51 of the instant application.

11. Claim 52 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claims 1 and 16 of U.S. Patent No. 6,423,198 B1. Claim 46, from which claim 52 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because the device of claim 16 of U.S. Patent No. 6,423,198 B1 provides the additional limitation of claim 52 of the instant application.

12. Claim 53 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claims 1 and 17 of U.S. Patent No. 6,423,198 B1. Claim 46, from which claim 53 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because the device of claim 17 of U.S. Patent No. 6,423,198 B1 provides the additional limitation of claim 53 of the instant application.

13. Claim 54 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claim 1 of U.S. Patent No. 6,423,198 B1 in view of Harrison et al. ("Capillary Electrophoresis and Sample Injection Systems integrated on a Planar Glass Chip," Anal. Chem. 1992, 64, 1926-1932) ('Harrison"). Claim 46, from which claim 54 depends, has been addressed above. The claims of U.S. Patent No. 6,423,198 B1 do not mention providing a lid for the substrate. Harrison

discloses a microfluidic substrate having a cover plate; that is, a lid. See the first paragrraph of Devices on page 1927. It would have been obvious to one with ordinary skill in the art at the time of the invention to provide a lid as taught by Harrison in the invention of claim 1 of U.S. Patent No. 6,423,198 B1 because a lid will protect the fluid from being contaminated during the separation or transport of substances.

14. Claim 56 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,423,198 B1. Claim 46, from which claim 56 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because a reservoir and a waste receptacle in fluid communication with electrolyte channel are implied since a supply channel, a supply port, a drain channel and a drain port are provided.

15. Claim 57 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claims 1 and 17 of U.S. Patent No. 6,423,198 B1. Claim 46, from which claim 57 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because the device of claim 17 of U.S. Patent No. 6,423,198 B1 provides the additional limitation of claim 57 of the instant application.

16. Claim 58 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,423,198 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of claim 1 of U.S. Patent No. 6,423,198 B1 uses a device that meets the limitations of claim 58 of the instant application.

17. Claim 60 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,423,198 B1. Claim 46, from which claim 60 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because providing a fourth channel intersecting the electrolyte channel at a third port disposed between the supply port and the drain port is just multiplying parts for a multiplied effect. For example, the fourth channel could be used to as a second supply channel for another set of samples to be analyzed with the device.

18. Claim 61 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,423,198 B1. Claim 46, from which claim 60 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because a first electrode and a second electrode as claimed are implied by claim 1 of

U.S. Patent No. 6,423,198 B1 since "injection of said sample plug into said electrolyte channel is accomplished electrokinetically by applying an electric field across said supply and drain channels ..."

19. Claim 62 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claims 4 and 12 of U.S. Patent No. 6,280,589 B1. Claim 61, from which claim 62 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because at least a third electrode as claimed is implied since claim 4 refers to an electric potential at a reservoir for the electrolyte channel.

20. Claim 63 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claims 5 and 12 of U.S. Patent No. 6,280,589 B1. Claim 62, from which claim 63 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because the additional limitation of claim 63 is meet by claim 5 of U.S. Patent No. 6,423,198 B1.

Double Patenting Rejections based on U.S. Patent No. 6,280,589 B1

21. Claims 46-48 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 12 of U.S. Patent No. 6,280,589 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the device of claim 12 of U.S. Patent No. 6,280,589 B1 meets the limitations of claims 46-48 of the instant application.

22. Claim 49 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 13 of U.S. Patent No. 6,280,589 B1. Claim 46, from which claim 49 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because the device of claim 13 of U.S. Patent No. 6,280,589 B1 meets the additional limitation of claim 49 of the instant application.

23. Claim 50 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 14 of U.S. Patent No. 6,280,589 B1. Claim 46, from which claim 50 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because the device of claim 14 of U.S. Patent No. 6,280,589 B1 meets the additional limitation of claim 50 of the instant application.

24. Claim 51 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 18 of U.S. Patent No. 6,280,589 B1. Claim 50, from which claim 51 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because the device of claim 18 of U.S. Patent No. 6,280,589 B1 meets the additional limitation of claim 51 of the instant application.

25. Claim 52 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 16 of U.S. Patent No. 6,280,589 B1. Claim 46, from which claim 52 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because the device of claim 16 of U.S. Patent No. 6,280,589 B1 meets the additional limitation of claim 52 of the instant application.

26. Claim 53 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 17 of U.S. Patent No. 6,280,589 B1. Claim 46, from which claim 53 depends, has been addressed above. Although the

conflicting claims are not identical, they are not patentably distinct from each other because the device of claim 17 of U.S. Patent No. 6,280,589 B1 meets the additional limitation of claim 53 of the instant application.

27. Claim 54 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claim 12 of U.S. Patent No. 6,280,589 B1 in view of Harrison et al. ("Capillary Electrophoresis and Sample Injection Systems integrated on a Planar Glass Chip," Anal. Chem. 1992, 64, 1926-1932) ('Harrison"). Claim 46, from which claim 54 depends, has been addressed above. The claims of U.S. Patent No. 6,280,589 B1 do not mention providing a lid for the substrate. Harrison discloses a microfluidic substrate having a cover plate; that is, a lid. See the first paragraph of Devices on page 1927. It would have been obvious to one with ordinary skill in the art at the time of the invention to provide a lid as taught by Harrison in the invention of claim 12 of U.S. Patent No. 6,280,589 B1 because a lid will protect the fluid from being contaminated during the separation or transport of substances.

28. Claim 56 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 12 of U.S. Patent No. 6,280,589 B1. Claim 46, from which claim 56 depends, has been addressed above. Although the

conflicting claims are not identical, they are not patentably distinct from each other because a reservoir and a waste receptacle in fluid communication with electrolyte channel are implied since a supply channel, a supply port, a drain channel and a drain port are provided.

29. Claim 57 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 17 of U.S. Patent No. 6,280,589 B1. Claim 46, from which claim 57 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because the device of claim 17 of U.S. Patent No. 6,280,589 B1 meets the additional limitation of claim 57 of the instant application.

30. Claims 58 and 59 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 12 of U.S. Patent No. 6,280,589 B1. Claim 46, from which claims 58 and 59 depend, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of U.S. Patent No. 6,280,589 B1 are silent on whether the supply channel and the drain channel are on the same dies or on different sides of the electrolyte channel. However, the supply channel and the drain

channel must be either on the same side or on different sides of the electrolyte channel. Hence, both claims 58 and 59 cannot be unobvious over claim 12 of U.S. Patent No. 6,280,589 B1. Furthermore, barring a contrary showing, such as unexpected results, whether the supply channel and the drain channel are on the same side of the electrolyte channel or on an opposite side thereof is just a design choice that has no bearing on the operation of device. It is in effect just a rearrangement of parts without functional consequence.

31. Claim 60 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 12 of U.S. Patent No. 6,280,589 B1. Claim 46, from which claim 60 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because providing a fourth channel intersecting the electrolyte channel at a third port disposed between the supply port and the drain port is just multiplying parts for a multiplied effect. For example, the fourth channel could be used to as a second supply channel for another set of samples to be analyzed with the device.

32. Claim 61 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of related claims 1 and claim 12 of U.S. Patent No. 6,280,589 B1. Claim 46, from which claim 60 depends, has

been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because a first electrode and a second electrode as claimed are implied by claim 1 of U.S. Patent No. 6,280,589 B1 since "the method comprises the step of electrokinetically injecting the sample as a sample plug into said electrolyte channel by applying an electric field across the supply and drain channels."

33. Claim 62 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claims 1 and 12 of U.S. Patent No. 6,280,589 B1. Claim 61, from which claim 62 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because at least a third electrode as claimed is implied since claim 1 states "wherein electrophoresis separation of the sample takes place in the electrolyte channel.

34. Claim 63 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claims 1, 6, and 12 of U.S. Patent No. 6,423,198 B1. Claim 62, from which claim 63 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because the additional limitation of claim 63 is meet by claim 6 of U.S. Patent No. 6,423,198 B1.

Claim Rejections - 35 USC § 102

35. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

36. Claims 46, 52, and 58 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Harrison et al. ("Capillary Electrophoresis and Sample Injection Systems integrated on a Planar Glass Chip," Anal. Chem. 1992, 64, 1926-1932). See the abstract; first paragrraph of Devices on page 1927; and Figures 1, 3, and 4.

Claim Objections

37. Claim 55 is objected to because of the following informality: in line 2 "al" should be -- a --. Appropriate correction is required.

Final Rejection

38. Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

39. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alex Noguerola
Primary Examiner
AU 1753
September 21, 2005